

AMENDMENTS

In the Claims

Please cancel claims 38-47 and 51 without prejudice.

REMARKS

Claims 28-47, 50, and 51 have been examined and stand rejected on various grounds. This amendment cancels claims 38-47 and 51 so that claims 28-37 and 50 remain pending. The objections and rejections are addressed below and in view of the preceding amendments and remarks made herein, the present application is believed to be in condition for allowance.

35 U.S.C. § 112, Second Paragraph

Claims 29, 30, 34, 35, 39, 40, 44, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In view of the above amendment canceling claims 38-47 and 51, the § 112 rejections of claims 39, 40, 44 and 45 are moot.

Applicants respectfully submit the Examiner is applying precedent incorrectly. The text quoted in the Office Action refers to rejections based on prior art references and whether structural limitations shall be given "weight" to distinguish the claims from the cited references. See *Ex parte Pfeiffer*¹. The case does not stand for the proposition as set forth in Office Action and it is improper to apply such a rule without proper grounds. In opposite to the Office Action, *Pfeiffer* indicates that "the patent statute [] impliedly permits recitations of structure in method claims. Manifestly, the mere inclusion of structure in a method claim does not of itself render the claim unstatutory or fatally defective."² Based on the foregoing, the principle relied upon to

¹ 782 O.G. 639, 641 (1962).

² *Id.*

reject the subject claims is therefore improper because it refers to art-based rejections and not rejections based on indefiniteness or § 112, paragraph 2.

Notwithstanding Applicants comments set forth above, claims 29, 30, 34 and 35 do not amount to claiming the mere "use" of a particular structure as the Office Action asserts. A review of the case cited in the Office Action and "mere use" cases, discussed below, indicate that claiming the mere use of a structure is something quite distinct from that which Applicants are claiming in the subject application.

Indeed, the Board of Appeals of the United States Patent Office (hereafter referred to as the "Board") decisions make clear that the "mere use" doctrine is distinct from the claims at issue. For example, in *Ex parte Erlich*³, the Board affirmed the Examiner's decision that claiming "a process for using monoclonal antibodies of Claim 4 to isolate and purify human fibroblast interferon" is violative of § 112, second paragraph.⁴ It is noteworthy that the dependent method claims in *Erlich* specifically recited the use of a structural element without providing any positive active steps.

The subject claims are easily distinguished from the claims at issue in *Erlich*. First, the subject claims do not recite the "use of" or "using" a particular structure. Second, there is no structure explicitly provided in the subject claims; consequently, there cannot be a use of a structural limitation or element because there is simply no structure provided. In opposite, a structural element was specified in *Pfeiffer* (the bag) as well as in *Erlich* (the monoclonal antibodies). To the extent the Examiner disagrees with Applicants, Applicants request the Examiner specify what structure is being "used" so that Applicants can more clearly respond to the Examiner's comments.

³ 1986 Pat. App. LEXIS 13; 3 U.S.P.Q.2D (BNA) 1011(1986).

⁴ Claims 6 and 7 respectively state: "[a] process for using monoclonal antibodies of Claim 4 to isolate and purify human fibroblast interferon" and "[a] process for using monoclonal antibodies of Claim 4 to identify human fibroblast interferon." *Id.* at 21.

Additionally, the subject claims do specify a positive active process step. The subject claims require emitting light in a particular way (claims 29 and 34 recite that the irradiating step is performed by emitting a light energy having a wavelength of about 240 nm to 280 nm; claims 30 and 35 recite that the irradiating step is performed by emitting a light energy having a wavelength in the red visible range). Thus, the subject dependent claims specify how the irradiating step is manipulated: instead of emitting light in all ranges as various light sources may do, light is emitted in a pre-selected defined range. Consequently, Applicants dependent claims provide a clear active step which manipulates the preceding steps by controlling the wavelength range.

Applicants also note the Office Action provides that "Applicant has demonstrated no manipulative difference in the attaching of the applicator to a red light source, rather than a 245-280 nm light source." However, this notion is not pertinent to the above rejection because claims directed to the red light source do not depend from the claims directed to the 245-280 light source or vice versa. Rather, the claims directed to the red light source depend from the broad independent claim and the claims to the 245-280 also depend from the broad independent claim. Applicants are not claiming that claim 30 depends from claim 29 or vice versa.

Based on the foregoing, Applicants acknowledge respectfully submit (1) the patent statutes permit structural limitations in method claims; (2) the application of the rule set forth in the Office Action is being incorrectly applied to the subject claims; (3) the "mere use" doctrine is not pertinent to the subject claims; and (4) the subject claims do provide active steps which properly depend from the other claims. Accordingly, Applicants request reconsideration and withdrawal of the rejections of claims 29, 30, 34 and 35 (the rejections of claims 39, 40, 44, and 45 being moot) under § 112, second paragraph.

35 U.S.C. § 102(b)

Claims 51 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,053,033 to Clarke (hereinafter referred to as "Clarke"). Claim 51 has been cancelled and consequently, the rejection of claim 51 is moot.

35 U.S.C. § 103(a)

Claims 28-47 and 50 stand rejected under 35 U.S.C. § 103 as being allegedly obvious over Clarke. Claims 38-47 have been cancelled and their rejections are now moot. The Office Action provides:

It would have been obvious to the artisan of ordinary skill to employ the method in bronchial tissue, esophigal [sic] tissue, or urethral tissue since these are equivalents and are all composed of smooth muscle cells that respond to the same irradiative methods as blood vessels, official notice of which has already been taken . . . and to employ the method in an astmatic [sic] lung, since there is no indication that the smooth muscle cells therein would respond differently than in non astmatic [sic] lung thus producing a method such as claimed.

Applicants respectfully disagree. The Office Action does not set forth a *prima facie* case of obviousness.

According to MPEP § 2142, "[t]he Examiner bears the initial burden of factually supporting a *prima facie* case of obviousness." To make a *prima facie* case of obviousness, three requirements must be met. First, there must be some suggestion or motivation to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Third, the reference(s) must teach or suggest all the claim limitations.⁵

Here, there is no motivation set forth within the four corners of Clarke (the primary and sole reference) to irradiate lung tissue as the subject claims require. Simply stated, Clarke does not provide motivation to use the device and method disclosed in Clarke and apply it as the

⁵ MPEP at § 2143.

subject claims require. This requirement cannot be overlooked and hence, reconsideration and withdrawal of the rejections is requested.

We acknowledge that the Examiner may take "official notice" of certain well known prior art or common knowledge. The MPEP provides that "[t]he examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being 'well-known' in the art."⁶ "If justified, the Examiner should not be obliged to spend time to produce documentary proof. If the knowledge is of such notorious character that official notice can be taken, it is sufficient so to state."⁷ However, "[i]f the applicant traverses such an assertion the examiner should cite a reference in support of his or her position."⁸ In the subject case, Applicants submit the motivation to treat the airway smooth muscle tissue as the Examiner proposes in not well known much less notorious or unquestionable. Accordingly, Applicants traverse the Examiner's assertion as to employ the method in bronchial tissue, airway smooth muscle tissue, and in an asthmatic lung.

Clarke is silent as to treating the walls of an airway or airways. Clarke also does not provide that airway tissue is the same as vasculature tissue. Clarke does not state such tissue will respond the same or that their environments are the same. Clarke thus does not provide motivation to apply such a method in the lung. Applicants further state official notice is not properly taken as to this issue because it is not well known to treat the lungs as Applicants claim. To the extent the Examiner disagrees, Applicants request that a reference be provided which discloses a method for treating a lung comprising irradiating the walls of an airway to cause debulking of the lung tissue over time.

Additionally, there must be a reasonable expectation of success. Regarding Clarke, the primary and sole reference, it does not provide any indication that light should be applied to the

⁶ MPEP § 2144.03 citing *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970).

⁷ MPEP § 2144.03 citing *In re Malcolm*, 129 F.2d 529 (CCPA 1942).

⁸ *Id.*

airway walls. Clarke, as the Office Action points out, teaches inhibiting restenosis of vascular smooth muscle cells following angioplasty. The figures in Clarke show treating the plaque and vascular smooth muscle cells --not UV radiation of airway wall tissue. While each of the vasculature and the airways contain smooth muscle cells at some level, there is no indication in Clarke that vasculature smooth muscle cells are identical to airway smooth muscle cells.

In fact, there is reason to suspect the Clarke method could fail if applied to the lung airways because the airways' structure and function are different than that of the blood vessels. For example, the airway wall has an epithelial lining, mucous glands and mucous ducts. None of these features are present in blood vessels. The airways also connect with different surrounding tissues than the blood vessel smooth muscle: certain airways are connected with cartilage and vasculature. Thus, the airways may absorb energy differently than the blood vessels.

Additionally, air and mucous are contained in the airways whereas blood is contained in the vasculature. The blood vessels also develop plaque, fat and other deposits which are quite distinct from the narrowing of airways found in reversible chronic obstructive pulmonary disease such as asthma. The above distinctions between the blood vessels and airways can provide for different optical properties including variations in light absorption, scattering and transmission which can result in different biological effects. In view of the above mentioned differences between blood vessels and the airways, the differences between the substances contained therein, and the phenomena that each tissue may respond differently to light irradiation, it is not clear there would be a reasonable likelihood that the method taught in Clarke would be successful if attempted in an airway.

Based on the foregoing, Applicants respectfully submit that the grounds for rejection of claims 28-37 and 50 under 35 U.S.C. § 103 have been overcome and request that the rejection be withdrawn. Claims 39-47 have been cancelled and consequently, their rejections are moot.

CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **435712000900**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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